

AMENDED SPECIFICATION

[0014] FIG. 1 is a side elevation view of a preferred low flow atrial-arterial shunt for pump-assisted myocardial revascularization without cardiopulmonary bypass, according to the present invention;

[0021] With reference to FIGS. 1-6, a preferred low flow atrial-arterial shunt 20 for pump-assisted myocardial revascularization without cardiopulmonary bypass, according to the present invention, comprises a short section of ¼" x 1/16" (6.4 mm x 1.6 mm) conventional cardiopulmonary bypass tubing 22 securely terminated at either end with a vented cannula adapter 24a, 24b. In the illustrated preferred embodiment, the ~~[[The]]~~ shunt 20 is used in conjunction with a conventional venous cannula 26, a conventional aortic cannula 28, and a conventional peristaltic or roller pump 30, which is preferably one of the peristaltic pumps found in a medical facility's existing cardiopulmonary bypass machine. The shunt 20, two cannulae 26, 28, and pump 30 can be used for left ventricular assist or right ventricular assist, or two shunts 20 can be used for biventricular assist (along with four cannulae and one or two pumps).

[0024] FIGS. 1-3 show the preferred shunt 20 in some detail. As mentioned above, the shunt 20 is a section of tubing 22 terminated at either end by the vented cannula adapters 24a, 24b. The section of tubing 22 is a short length (approximately 6 ft/2 m) of ¼" inner diameter ("ID") x 1/16" wall thickness (6.4 mm x 1.6 mm) conventional cardiopulmonary bypass tubing, *i.e.*, clear, flexible tubing suitable for sterile medical use. The cannula adapters 24a, 24b are made of translucent, hard plastic, and are cylindrical in overall shape. Each has a longitudinal passageway ~~[[50]]~~ (e.g., 50), and includes a ¼" ID section ~~[[52]]~~ 52a, 52b for attachment to the tubing 22, and a 3/8" ID section ~~[[54]]~~ 54a, 54b for attachment to the cannulae 26, 28. Both sections ~~[[52, 54]]~~ (e.g., 52a and 54b) are of the luer-lock type for ease of connection, although other connection types may also be used. The cannula adapters 24a, 24b also each include a vent ~~[[56]]~~ 56a, 56b, which provides a side opening down through to the passageway ~~[[50]]~~ (e.g., 50). The vents ~~[[56]]~~ (56a, 56b) are sealed with removable, plastic, knurled caps ~~[[58]]~~ 58a, 58b, which include inner threads ~~[[60]]~~ (e.g., 60) for securely engaging a pair of protuberances ~~[[62]]~~ (e.g., 62) on the vents ~~[[56]]~~ 56a, 56b, and a neck plug ~~[[64]]~~ (e.g., 64) for enhanced sealing.

[0025] To assemble the shunt 20, the tubing 22 is cut to the appropriate length, and the adapters 24a, 24b (which are identical in the preferred embodiment) are connected to the tubing 22 by inserting the 1/4" ID sections 52 into the ends of the tubing. The tubing 22 is then tightly secured to the adapters 24a, 24b by way of plastic cable clamps [[64]] positioned between the luer-lock flanges. Lastly, the shunt 20 is sterile packaged, *e.g.*, in a standard, sealed, disposable, easily-opened container such as a pouch, either by itself or with another shunt for biventricular assist. (Because such sterile packaging is well known, it is not shown in the ~~drawings~~ drawing.)

[0030] _____ To use the shunt 20, the patient is prepped and his or her heart is accessed, according to standard medical practices. This may include the IV administration of Heparin at a dose of 10,000 IU.

[0031] _____ Next, the preferred venous cannula 26 (a 20Fr, angled, conventional venous cannula) is conventionally surgically attached to the left atrium 40 (assuming a left ventricular assist), and the aortic cannula 28 (a 22Fr conventional aortic cannula) is conventionally surgically attached to the aorta 44. Both cannulae 26, 28 are purged during the surgical connection process to prevent air from entering the blood stream, if necessary, and both are initially clamped with standard clamps [[90]] 90a, 90b.

[0032] _____ Next, the vented cannula adapters 24a, 24b are securely attached to the cannulae 26, 28, respectively.

[0033] _____ Subsequently, the shunt 20 is primed. To do so, the clamp [[90]] 90a on the venous cannula 26 is left in place, the cap [[58]] 58a on the adapter 24a is opened or removed, and the clamp [[90]] 90b on the aortic cannula 28 is unclamped. Since the aorta end is at a higher pressure than the left atrium end, blood flows from the aorta 44 through the tubing 22 and out the vent [[56]] 56a on the adapter 24a. This forces the air in the tubing 22 out through the vent [[56]] 56a. The tubing 22 may be physically manipulated to dislodge any trapped air bubbles. Subsequently, the cap [[58]] 58a is put back in place, and the clamp [[90]] 90b on the aortic cannula 28 may be reclamped.

[0034] _____ Next, the shunt is placed in the pump 30. As mentioned above, most cardiopulmonary bypass machines, such as those found in most medical facilities, have one or more standard peristaltic pumps like 30. These pumps are typically modular, such that they can

be removed from the bypass machine and used remotely. According to the present invention, one of those pumps [[30 is]] can be removed from a bypass machine, and is set up near the patient (before the operation, of course). In fact, the shunt 20 is purposefully made short so that the distance between the patient and the pump 30 is necessarily minimized. This reduces the volume of blood needed to use the pump, thereby eliminating the need for extra blood, minimizing the pump's effect on the blood, and increasing the pump's effectiveness.

[0035] With the pump 30 in place near the patient, the middle part of the shunt tubing 22 is placed in the pump 30, *i.e.*, with the tubing lying against the pump raceway and the pump roller head against the tubing. The pump 30 is closed or otherwise prepared for use. Then, the clamps [[90]] 90a, 90b on the cannulae 26, 28 are unclamped, and the pump 30 is activated. At some point during the process, it may be necessary to use the vent on the adapter 24b to further purge the tubing 22 of air.

[0039] For biventricular assist, two shunts [[20]] are used, one in the manner as shown in FIG. 5, and one in the manner as shown in FIG. 6. Two peristaltic pumps [[30]] can be used, one for each shunt [[20]], or a single peristaltic pump [[30]] can be used, provided [[it]] the pump is capable of holding and acting on two tubes [[22]], *e.g.*, pumping around 3 liters/minute on both lines.

[0039a] Each cap 58a, 58b can be thought of as a sealing means for selectively opening and closing a vent 56a, 56b for priming the shunt.